

K970882



JUN 24 1997

1100 Northside Drive Atlanta, Georgia 30318

February 27, 1997

## Premarket Notification [510(k)] Summary

**Submitter:** American Medical Devices, Inc  
1100 Northside Drive  
Atlanta, GA 30318  
Phone: (404) 815-5233  
Fax: (404) 815-5235

**Official Correspondent:** Frank J. Tighe

**Trade Name:** The American Medical Devices, Inc., 19 and 20 Ga. Endolight™  
End Irrigating Endo-Illuminator.

**Common Name:** Fiberoptic End Irrigating Endo-Illuminator

**Registration Number:** We have registered but have not received our application  
back as of this date.

**Class:** Class II

**Class Name:** We were unable to find the device listed in the classification  
regulations, 21 CFR Parts 862-892 [807.87 (c)].

**Panel:** Ophthalmic

**Product Code:** MPA

Page 1 Summary

11-Free  
793-1473

Direct  
404-815-5233

Facsimile  
404-815-5235

Internet  
ftighe@americanmedicaldevices.com

**Device Description:** The American Medical Devices, Inc 19 and 20 ga. Endolight™ End Irrigating Endo-Illuminators are for illumination and irrigation/aspiration during surgery. It consists of a stainless steel needle, delrin handpiece, PMMA fiberoptic fiber with plastic cladding, aluminum connector, and silastic tubing with luer lock connector. It connects to any conventional light source via an aluminum accessory adapter, which is packaged separately. This device also connects to any standard syringe with a male luer lock. The surgeon can then use the device to irrigate and aspirate while illuminating. Please see Device Replica Diagram in Appendix C.

**Statement of indications for use.** - For illumination and irrigation/aspiration during surgery.

**Substantial Equivalence Comparison**

	American Medical Devices, Inc.	Gamp & Assoc	Grieshaber	Infinitech
Packaging Tyvek to Poly	X	X	X	X
For irrigation/illumination During surgery	X	X	X	X
Materials: Stainless Steel Needle, PMMA Fiberoptic Fiber, Delrin Handpiece , Luer Lock Connector, Silastic Tubing	X	X	X	X
Aluminum Connector	X	X	X	X
Sterilization ETO	X	X	X	X

**Sterility**

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method

Packaging Material: Tyvek Pouch with a Ploymylar Sheath.

The SAL is 10 to the -6.

The maximum levels of residues of **ethylene oxide:** 25 parts per million; **ethylene chlorohydrin:** 25 parts per million and **ethylene glycol:** 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

**Pyrogens:** We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 21 1997

Mr. Frank J. Tighe  
American Medical Devices, Inc.  
1100 Northside Dr.  
Atlanta, GA 30318

Re: K970882  
Trade Name: Endolight™ End Irrigating  
Endo-Illuminator (19 and 20 GA.)  
Regulatory Class: II  
Product Code: 86 MPA  
Dated: June 9, 1997  
Received: June 13, 1997

Dear Mr. Tighe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K970882



1100 Northside Drive Atlanta, Georgia 30318

(510(k) Number (if known): K970882

Device Name: Endolight™ End Irrigating Endo-Illuminator (19 and 20 Ga.)

Indications for Use:

For illumination and irrigation/aspiration during surgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use       

(Optional Format 1-2-96)

*Bruce Owen*

(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number   K970882  

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